Complete Summary

GUIDELINE TITLE

Cervical cancer screening.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Cervical cancer screening. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 Jun. 38 p. [41 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Cervical cancer screening. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Aug. 29 p.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Cervical cancer

GUIDELINE CATEGORY

Counseling
Prevention
Risk Assessment
Screening

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To increase the percentage of women who are up-to-date for cervical cancer screening
- To improve the effectiveness of patient education by taking advantage of regular opportunities to inform women of the need for cervical Papanicolaou (Pap) smear screening

TARGET POPULATION

Adult women age 21 or older or with the onset of sexual activity

Note: Women with complaints secondary to the gynecological system lie outside the scope of this guideline.

INTERVENTIONS AND PRACTICES CONSIDERED

1. Education and counseling about cervical cancer screening
2. Cervical cytology screening (Papanicolaou [Pap] smears [traditional and liquid-based cytology])
3. Human papilloma virus (HPV) deoxyribonucleic acid (DNA) screening (if available)
4. Patient notification and follow-up

MAJOR OUTCOMES CONSIDERED

- Effect of prescreening educational and counseling activities on percentage of women presenting for cervical Papanicolaou (Pap) smear screening
- Predictive value of Pap smears
- Benefits of Pap smear procedures, techniques, and various screening intervals
- Incidence of cervical cancer at screening intervals of one, two, and three years
- Impact of screening intervals on incidence of morbidity or mortality from cervical dysplasia
- Mortality due to cervical cancer
- Disadvantages and adverse effects of Pap smear screening

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results

from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

   Class A:

   - Randomized, controlled trial

   Class B:

   - Cohort study

   Class C:

   - Nonrandomized trial with concurrent or historical controls
   - Case-control study
   - Study of sensitivity and specificity of a diagnostic test
   - Population-based descriptive study

   Class D:

   - Cross-sectional study
   - Case series
   - Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports

   Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developer reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eight-week period of "Critical Review."

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group: Second Draft

Following the completion of the "Critical Review" period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary, and a written response is prepared to address each of the suggestions received from medical groups. Two members of the Preventive Services Steering Committee carefully review the Critical Review input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of two questions: (1) Have the concerns of the medical groups been adequately addressed? (2) Are the medical groups willing and able to implement the guideline? The committee then either approves the guideline for pilot testing as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Medical groups introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occur throughout the pilot test phase, which usually lasts for three months. Comments and suggestions are solicited in the same manner as used during the "Critical Review" phase.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Preventive Services Steering Committee reviews the revised guideline and approves it for implementation.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for the cervical cancer screening are presented in the form of an algorithm with a total of 32 components, accompanied by detailed annotations. An algorithm is provided for: Cervical Cancer Screening Page 1 and Page 2. Clinical Highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) and conclusion grade (I-III, Not Assignable) definitions are repeated at the end of the "Major Recommendations" field.

Clinical Highlights

1. Screening need not be performed for women who have had a hysterectomy for benign disease, provided they have no history of cervical intraepithelial neoplasia (CIN) 2 or CIN 3. (Annotation #4 - refer to the original guideline document, annotations #5, 7, and 8)
2. Women with a history of CIN 2/3 prior to but not as the indication for hysterectomy should be screened until three consecutive, technically satisfactory normal/negative vaginal cytology tests with no abnormal/positive cytology test within a ten-year period are achieved. (Annotation #7)
3. Initially all women should have annual cervical cancer screening beginning at age 21 or at three years after the onset of sexual activity. (Annotation #10)
4. It is appropriate to resume cervical cancer screening in a woman age 65 and older who has a new sexual partner. (Annotation #10)
5. After three consecutive normal screenings, and no dysplasia within the last five years, women may have their screening performed less frequently at the discretion of the clinician and patient. (Annotation #12, 29)

Cervical Cancer Screening Algorithm Annotations Page 1 and Page 2

1. Prescreening Educational and Counseling Activities

   Employer, School and Community Education Activities

   This group, through this guideline, acknowledges the crucial role played by education and outreach efforts in helping to increase the number of age-appropriate women who present themselves for regular cervical cancer screening, thereby reducing the incidence of cervical cancer mortality.

   The following are some ideas for employers, schools, and community organizations:

   Awareness initiative programming, including:

   - Posters for company bulletin boards
   - Payroll stuffers with general screening information
   - General screening information "tents" for tables in reception areas, cafeterias, employee lounges, restrooms, locker rooms, and other such places

   Educational initiative programming, including:

   - Articles in employee newsletters, magazines, and/or newspapers
   - Brown-bag lunch seminars, health fairs
   - Direct-mail campaigns with screening information sent to all eligible employees and health plan enrollees

   Behavioral change initiative programming, including:

   - Financial incentive plans, such as employer group programs, which reward enrollees who practice a range of preventive health behaviors including regular cervical cancer screening

- Removal of any time, transportation, or other pragmatic barriers to screening
- Making a high-level management commitment to cervical cancer screening and other prevention programs

Information on the importance of regular cervical cancer screening can be included as part of broader health promotion/disease prevention initiatives, that include not only cancer prevention education, but also address heart disease and appropriate health care utilization as well. Some employers and health maintenance organizations around the country have also launched successful Women's Health Campaigns, which include cervical cancer screening along with other prominent health issues for women, such as breast cancer detection, smoking, exercise, and so on.

Provider Prescreening Educational and Counseling Activities

Materials such as brochures, posters, "special message" prescription pads, chart reminders, and so on can help support the provider in her/his role as patient counselor/educator. Face-to-face opportunities to encourage women - especially those who haven't had a cervical cancer screen recently or ever - to take advantage of this important and potentially life-saving procedure are instrumental in improving screening rates, thereby reducing cervical cancer mortality.

Suggested health care provider activities include:

- Use brochures, posters, and direct-mail materials to recruit women for cervical cancer screening.
- Have a process in place to communicate results to patients following cervical cancer screening, such as:
    - Letter/postcard re: need for repeat cervical cancer screening
    - Letter/postcard re: normal cervical cancer screening results
    - Letter/postcard re: cervical cancer screening findings necessitate repeat cervical cancer screening in six months
    - Letter/postcard re: cervical cancer screening findings necessitate further diagnostic follow-up
- Have available materials such as brochures, booklets, or videos regarding findings, disorders, and follow-up diagnostic procedures.
- Have a process in place to remind patients regarding their next appointment for cervical cancer screening, including any patient-specific instructions.
- Have a process in place to identify women who are overdue for cervical cancer screening and contact them to encourage them to come in for screening. Techniques, such as follow-up phone calls or opportunistic screening by providers may be effective. Combinations of modified invitation, written reminders, and phone reminders have been shown to double attendance for screening and triple the number of cytologic abnormalities detected.
- Have available support and awareness-building opportunities for providers to assist them in the role of patient "recruiter" (e.g., chart reminders, special prescription pads, continuing medical education gatherings).

- As a last resort, consideration could be given to self-sampling methods.

Evidence supporting this recommendation is of classes: A, C, D, M, R

2. Does Patient Have Human Immunodeficiency Virus (HIV)?

   As advocated in the 1999 U.S. Public Health Services/ Infectious Diseases Society of America (USPHS/IDSA) guideline for prevention of opportunistic infection in HIV persons, annual screening is recommended after two normal cervical cancer screenings six months apart after the initial diagnosis of HIV.

   Evidence supporting this recommendation is of classes: M, R

5. Was Carcinoma in Situ (CIS) or Cervical Carcinoma Present at the Time of Hysterectomy?

   Women who have had a hysterectomy for carcinoma in situ or invasive cancer should be monitored clinically on at least an annual basis with pelvic exam and vaginal cytology test from the vaginal apex. Immediately following hysterectomy for these indications, a vaginal cytology test should be performed on a more frequent basis.

7. Any History of CIN 2/3?

   Women with a history of CIN 2/3 prior to, but not as the indication for, hysterectomy should be screened until three documented consecutive, technically satisfactory normal/negative vaginal cytology tests with no abnormal/positive cytology test within a ten-year period are achieved.

8. Cervical Cancer Screening Not Required

   Further cytologic examination is not required for women who have undergone a hysterectomy with removal of cervix for benign disease.

   Evidence supporting this recommendation is of class: R

9. Perform Vaginal Cytologic Examinations

   Perform vaginal cytologic examinations until three documented consecutive technically satisfactory normal/negative tests are obtained within a ten-year period.

10. Initiation and Cessation of Screening

    Initiation of Screening

    Cervical cancer screening should be initiated on all women beginning at age 21 or 3 years after the onset of sexual activity. In the asymptomatic patient

there is no known benefit to performing a pelvic exam as a screening procedure for gynecological disease.

Cessation of Screening

In women who have had previous adequate screening, there is no clear evidence of the need for cervical cancer screening in women over 65 years of age. However, there is still a significant incidence of cervical cancer in this age group in women who have not had previous screening. Cervical cancer screening may be performed with mutual consent of patient and provider and should not be performed within less than 2- to 3-year intervals because of the risk of false positives. Please note as well, women who were exposed to diethylstilbestrol (DES) in utero and women who are immunosuppressed should continue Pap smear cervical cancer screening as long as they are in good health.

There is no consensus in the literature on whether there should be an upper age limit for cervical cancer screening. The United States Preventive Services Task Force recommends discontinuing screening at age 65 years if the physician can document previous Papanicolaou screening in which smears have been consistently normal. The American Cancer Society recommends triennial screening with no upper age limit. The Canadian Task Force on Cervical Cancer Screening Programs recommends that women over age 69 years who have had at least two satisfactory normal Pap smears and no significant epithelial abnormality in the last nine years and who have never had biopsy-confirmed dysplasia or carcinoma in situ can be dropped from the cytology screening program. After in-depth discussion, it is this group's recommendation that cervical cancer screening may be discontinued after age 65 at the mutual consent of the patient and provider, given that there has been previous adequate screening. A recent report from the Heart and Estrogen/Progestin Replacement Study (HERS) suggests that Pap smears performed within two years of normal cytologic results have a poor positive predictive value. By logical extension, the work group recommends that women over age 65 who have a new sexual partner resume Pap smear cervical cancer screening within three years, though data to support this are currently lacking.

Women over 65 years of age with a minimum of 3 consecutive normal cervical cancer screenings in the past 10 years and who are not otherwise at high risk for cervical cancer may cease routine screening [Conclusion Grade II: See Conclusion Grading Worksheet -- Appendix A -- Annotation #10 (Cessation of Screening) in the original guideline document]

11. Previous Initial Adequate Screening
12. Screening Intervals (After Initial Screen)

Adequate screening is defined as within the last 5 years the patient has had:

- 3 consecutive normal, (no dysplasia or atypia), technically satisfactory cervical cancer screenings within the last 5 years

The American College of Obstetricians and Gynecologists (ACOG) and many other national medical organizations recommend that a woman who has three consecutive normal cervical cancer screenings at 1-year intervals may, in consultation with her physician, decrease the frequency of screening to every 2 to 3 years.

Changing the frequency of screening from yearly up to three years should not result in significant excess incidence of morbidity or mortality from cervical dysplasia, even for so-called high-risk women, as long as:

- The woman has a documented history of negative cytology screenings
- Cytopathology laboratories continue to have a low rate of false negative reports
- The patient complies with the recommended frequency for cervical cancer screening up to three years

A recent workshop co-sponsored by National Institute of Health (NIH), National Cancer Institute (NCI), American Society for Colposcopy and Cervical Pathology (ASCCP), and the American Cancer Society (ACS) provided consensus recommendations for cervical cancer screening based on a literature review, expert opinion, and unpublished results from large ongoing screening studies. As a result of this workshop, a new recommendation emerged for screening women age 30 or older. Women in this age category who are high-risk human papilloma virus (HPV) deoxyribonucleic acid (DNA) negative and have a cervical cytology result of "negative for intraepithelial lesion or malignancy" should not be re-screened before 3 years.

14. Perform cervical cytology screening including HPV DNA screening (if available)

Cervical cancer screening is recommended as follows for patients age 30 and older:

- Every one to two years if previous cervical cytology reports have been negative and the patient's HPV status is unknown/untested
- Every three years if previous cervical cytology reports and high-risk HPV DNA tests are negative

To enhance the likelihood of obtaining cells from the squamocolumnar junction, the following procedure is recommended:

- It would be best if the patient could be instructed not to use a vaginal douche or any type of lubricant for 24 hours before a cervical cytology screening is performed. However, failure to adhere to this recommendation should not preclude a patient from receiving such screening.
- Cytological specimens should be obtained with a non-lubricated speculum before a bimanual pelvic examination, if the latter is performed.
- The cervix and the area of the vagina adjacent to the cervix must be fully visible when the specimen is obtained.

A. For Liquid Based Cytology (LBC)
    - Collection technique may vary by manufacturer.
    - LBC has been shown to have higher sensitivity and specificity for both low and high grade dysplasia.

B. HPV as an Adjunct to Cervical Cytology

    HPV DNA testing may be used as an adjunct to cervical cytology for screening women age 30 and older to help minimize unnecessary evaluations and treatments

C. For Traditional Pap Smears
    - The ectocervix and endocervix should be sampled separately (spatula first, cytobrush last).
    - A plastic Ayre spatula, preferably with an extended tip, or a wooden spatula is rotated with pressure over the entire ectocervix.
    - The standard method for sampling the endocervix is with an endocervical brush, which enhances cell recovery. Proper instructions for use of an endocervical brush include:
        - Sample ectocervical region first using ectocervical spatula.
        - Insert brush into the endocervical canal and rotate one half to two full turns.
        - Transfer collected cells to a glass slide with a frosted end by gently rolling and twisting brush against microscope slide, taking care to spread the material thinly (material must be spread thinly to allow for microscopic interpretation) and then apply cytology fixative. Other devices such as the pointed Ayre spatula also sample the transformation zone. This device is gently inserted into the endocervix and rotated slowly one to two full turns.
        - The slide is fixed immediately to prevent drying, either by immersing it in a jar of 95% ethyl alcohol and fixing for 15 minutes, spraying with aerosol or pump fixative while holding the spray can at least 10 to 12 inches from the slide, or flooding with the liquid fixative. Slides fixed in 95% ethyl alcohol can be transported to the laboratory in the alcohol bath or allowed to air-dry following fixation. Smears fixed with aerosol or flooding must be air-dried before sending to the laboratory.

Evidence supporting this recommendation is of classes: C, M, R

15. Cervix Normal?

A normal looking cervix is defined in any standard medical text. The presence of eversion and/or Nabothian cysts does not constitute an abnormality in this context. If a lesion is grossly visible, cervical cytology alone does not constitute adequate evaluation; biopsy with or without colposcopy should be done.

19. Cytology Normal?

In order to achieve a more consistent manner of cervical cytology reporting, it is highly recommended that all providers and their affiliated laboratories adopt the 2001 Bethesda system of nomenclature for cytology interpretation as their system of reporting cervical cytology results.

Women should be notified of cervical cancer screening results in a manner that is mutually agreeable to the provider and patient. The authoring work group strongly recommends contacting all patients with the results of their cervical cancer screening, whether normal or abnormal. In certain circumstances, state/regional laws may regulate the manner by which a patient is contacted with results of laboratory testing. Contact your state/regional health department for more information.

At the time of results notification, a natural opportunity exists for counseling and education specific to the patient's needs. Women whose cervical cancer screening results are abnormal should receive additional information about their results, including the need for follow-up via a repeat cervical cancer screen or other diagnostic procedure. Written educational materials could also be offered at this time. Every opportunity should be taken to stress the importance of continued regular cervical cancer screening with all women eligible for screening. An opportune time to reinforce this message with women exists during results notification.

Evidence supporting this recommendation is of class: R

22. Repeat Cervical Cytology Screening and HPV DNA Screening in 6 to 12 Months

The 2001 Bethesda system of nomenclature for cytology interpretation (see Annotation #29, "Evaluate Patient Education Needs and Discuss Patient Risk Factors/Respond to Patient Questions and Concerns/Notify Patient of Results and Follow-Up Recommendations") includes an evaluative component describing the adequacy of the specimen. This component is further subdivided into two categories:

- Satisfactory for evaluation
- Unsatisfactory for evaluation

Because this guideline recommends that cervical cancer screening may be performed on an every one-to-three-year basis, this work group is also recommending that any cervical cancer screen reported as unsatisfactory for evaluation should be repeated no sooner than eight weeks after the initial cytology screen but before twelve months.

If a reasonable effort to obtain a cervical specimen results in continued "absence of endocervical" cells, the cytology report should be considered normal and need not be repeated more frequently than the standard recommendation. In those patients who are postmenopausal and whose cytology specimens are limited by the "absence of endocervical cells," such

cervical cancer screenings need not be repeated more frequently than the standard recommendation.

Evidence supporting this recommendation is of class: R

24. Patient Age 21 to 29 or 3 Years Post-Onset of Sexual Activity?

    The American Cancer Society (ACS) recommends annual cervical cancer screening for this group of patients. American College of Obstetricians and Gynecologists (ACOG) recommends a longer interval (every 2 years or at the discretion of the clinician and patient) when three consecutive negative cervical cytology screenings have been achieved.

25. Perform Cervical Cytology

    For information on how to perform cervical cytology screening, see Annotation #14.

26. Cervix Normal?

    A normal looking cervix is defined in any standard medical text. The presence of eversion and/or Nabothian cysts does not constitute an abnormality in this context. It a lesion is grossly visible, cervical cytology alone does not constitute adequate evaluation; biopsy with or without colposcopy should be done.

29. Evaluate Patient Education Needs and Discuss Patient Risk Factors/Respond to Patient Questions and Concerns/Notify Patient of Results and Follow-up Recommendations

    Women who have many risk factors have a greater need to be screened, but do not need to be screened more frequently as long as their prior cervical cancer screening have been normal. Below is a table of risk factors.

    The HIV-positive female has a much higher risk of developing cervical cancer and therefore should be screened annually.

    Women should be notified of cervical cancer screening results in a manner that is mutually agreeable to the provider and patient. The authoring work group strongly recommends contacting all patients with the results of their cervical cancer screening results, whether normal or abnormal. In certain circumstances, state/regional laws may regulate the manner by which a patient is contacted with results of laboratory testing. Contact your state/regional health department for more information.

    At the time of results notification, a natural opportunity exists for counseling and education specific to the patient's needs. Women whose cervical cancer screening results are abnormal should receive additional information about their results, including the need for follow-up via a repeat cervical cancer screen or other diagnostic procedure. Written educational materials could also be offered at this time. Every opportunity should be taken to stress the

importance of continued regular, periodic cervical cancer screening with all women eligible for screening. An opportune time to reinforce this message with women exists during results notification.

Risk Factors

Relative Risks (Case Control Studies) for Cervical Cancer by Specific Risk Factor:

RR = relative risk

- HIV: RR = very high
- Moderate Dysplasia on cervical cancer screen within past five years: RR = very high
- Intercourse within 1 year of menarche: RR = 26
- Intercourse under age 16 years: RR = 16
- No Prior Screening: RR = 10
- Human papilloma virus (HPV) (depending on subtyping): RR = 2.5-30
- Six or more lifetime sexual partners: RR = 5
- Low socioeconomic class: RR = 5
- Race (African-American vs. Caucasian): RR = 2.5
- Smoking: RR = 2
- Oral contraceptive use: RR = 1.2-1.5
- Barrier Contraception: RR = 0.6

Note: A relative risk of 1.0 would indicate no increased probability of negative outcome, whereas RR of less than 1.0 means an actual protective effect may be present. RR of 10 means a tenfold increase. Overall risk for reproductive age non-hysterectomized American women to develop cervical cancer is about one in 5,200 per year, or 0.02%.

Patient Communication

Reminder postcards, letters, and telephone calls are integral components of a cervical cancer screening initiative:

- Communication tools to inform women of cervical cancer screening results
- Explanations of next steps necessary to further diagnose abnormalities
- Reminders regarding completing appropriate tests and/or examinations
- Routine reminders for periodic cervical cancer screening

Evidence supporting this recommendation is of classes: C, D, M, R

Definitions:

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with

negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

   Class A:

   - Randomized, controlled trial

   Class B:

   - Cohort study

   Class C:

   - Nonrandomized trial with concurrent or historical controls
   - Case-control study
   - Study of sensitivity and specificity of a diagnostic test
   - Population-based descriptive study

   Class D:

   - Cross-sectional study
   - Case series
   - Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports

   Class M:

   - Meta-analysis

- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

CLINICAL ALGORITHM(S)

A detailed and annotated clinical algorithm is provided for Cervical Cancer Screening Page 1 and Page 2.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains an annotated bibliography and discussion of the evidence supporting each recommendation. The type of supporting evidence is classified for selected recommendations (see "Major Recommendations" field).

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Increased percentage of women who are up-to-date for cervical cancer screening
- Improved effectiveness of patient education by taking advantage of regular opportunities to inform women of the need for cervical Pap smear screening

Subgroups Most Likely to Benefit

Women at high risk of cervical cancer, especially women who are human immunodeficiency virus (HIV)-positive, women who have had moderate dysplasia on Papanicolaou (Pap) smear within the past five years, women who had intercourse within 1 year of menarche, and women with no prior screening (see "Major Recommendations" for additional risk factors)

POTENTIAL HARMS

Pap smears can result in false-positive and false-negative results.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.
- There is no consensus in the literature on whether there should be an upper age limit for cervical cancer screening.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

IMPLEMENTATION TOOLS

Clinical Algorithm
Pocket Guide/Reference Cards
Quality Measures

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED NQMC MEASURES

- Cervical cancer screening: percentage of women age 21 through 64 years continuously enrolled during the last twelve months having at least one cervical Pap smear during the past three years.
- Cervical cancer screening: percentage of women age 21 through 64 years seen at least once in the clinic during the past two years who are up-to-date for cervical cancer screening.
- Cervical cancer screening: percentage of women having completed their cervical cancer screening within six months of a reminder sent to them.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Cervical cancer screening. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 Jun. 38 p. [41 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1994 Sep (revised 2005 Jun)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

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GUIDELINE COMMITTEE

Preventive Services Steering Committee

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GUIDELINE STATUS

This is the current release of the guideline.

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GUIDELINE AVAILABILITY

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- ICSI pocket guidelines. April 2004 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2004. 404 p.

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PATIENT RESOURCES

None available

NGC STATUS

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